

CLAIMS

1. An electro-dose constituting a medical powder intended for use in a dry powder inhaler, said electro-dose being prepared from an electro-powder constituting an active powder substance or a dry powder medical formulation, which is metered onto a device member forming a dose carrier, giving a fine particle fraction (FPF) presenting of the order 50 % or more of its content with a particle size between 0.5-5 μm , the dose further presenting an optimized porosity of 75 to 99.9 %.

10 2. The electro-dose according to claim 1, said metered electro-dose constituting an electro-powder providing electrostatic properties regarding absolute specific charge per mass after charging of the order 0.1 to 25 $\mu\text{C/g}$ and presents a charge decay rate constant Q_{50} of more than 0.1 sec with a tap density of less than 0.8 g/ml and a water activity a_w of less than 0.5.

15 3. The electro-dose according to claim 1, said metered electro-powder after a mechanical vibration of the dose receiving device member during a metering operation being adjusted to a porosity presenting a value in percent between 75 and 99.9.

20 4. The electro-dose according to claim 1, said metered electro-dose, after analysis by a laser triangular method for a total volume calculation and a HPLC or weighing operation for determining the electro-dose mass, the porosity of the electro-dose, calculated in percent as $100 - 100 \times (\text{Density}_{\text{electro-dose}} / \text{Density}_{\text{electro-powder}})$, presenting a value in percent between 75 and 99.9.

25 5. The electro-dose according to claim 1, said metered electro-dose having, onto a surface area of said device member which forms a dose carrier, a height less than 800 μm .

30 6. The electro-dose according to claim 1, said metered electro-dose by using mechanical vibrations of the device member being adjusted to a porosity having in percent a value between 75 and 99.9.

7. The electro-dose according to claim 1, said metered electro-dose, by using a frequency oscillation in an electrical field, being adjusted to a porosity having in percent a value between 75 and 99.9.

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8. A method for preparing a metered electro-dose of electro-powder for administration into the deep or upper lung airways by oral inhalation by a dry powder inhaler device, comprising the steps of:

10 dosing a medical powder, being a preparation of chemical and biological substance forming an electro-powder onto a device member constituting a dose carrier

forming of a metered electro-dose bed onto said dose carrier using electrical field technology;

combining said electrical field technology with a mechanical vibration and/or an applied electrical frequency;

analyzing said metered electro-dose bed regarding dose height, dose area, dose de-agglomeration, dose mass, dose density, dose porosity;

comparing analysis result with predefined dosing parameters for deciding that said metered electro-dose on the dose carrier complies with basic requirements for administration by the inhaler.

9. The method according to claim 8, comprising the further step of controlling that said metered electro-dose has an optimized porosity of 75 to 99.9 %.

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10. The method according to claim 8, comprising the further step of utilizing mechanical vibration of the dose receiving device member during dosing operation to adjust said metered electro-dose powder porosity to an optimized value in percent between 75 and 99.9.

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11. The method according to claim 8, comprising the further step of analyzing said metered electro-dose by a laser triangular method and a HPLC or weighing operation for a total volume calculation to determine

electro-dose mass in order to calculate the electro-dose powder porosity in percent as $D_p = 100 - 100 \times (\text{density}_{\text{electro-dose}} / \text{density}_{\text{electro-powder}})$ obtaining an optimized value in percent between 75 and 99.

5 12. The method according to claim 8, comprising the further step of preparing said metered electro-dose onto a surface area of said device member, to obtain an electro-dose height of less than 800 μm .

10 13. The method according to claim 12, comprising the further step of controlling said metered electro-dose height by means of a triangular laser measuring instrument.

14. The method according to claim 8, comprising the further step of additionally preparing said metered electro-dose by using an oscillating electrical field to adjust the porosity of said electro-dose to an optimized value in percent of 75 to 99.9.

15. The method according to claim 8, comprising the further step of preparing said electro-dose using at least one active electrical filter with a control potential switched on and off within a voltage range $V_{\text{low electrical field}} \leq V_{\text{filter}} \leq V_{\text{device member}}$ during a metering process and using an opening area per controlled opening of the active electrical filter in a range of $0.02 \leq \text{Filter opening} \leq 75 \text{ mm}^2$.

25 16. The method according to claim 8, comprising the further step of measuring metered electro-dose mass by draining its electrostatic charge into a electrometer thereby to determine a specific charge in $\mu\text{C/g}_{\text{electro-powder}}$.

30 17. The method according to claim 8, comprising the further step of measuring metered electro-dose height using a contrast analyzing method and controlling height of said electro-dose to be less than 800 μm .

18 The method according to claim 8, comprising the further step of measuring metered electro-dose height using a laser triangulation method and controlling height of said electro-dose to be less than 800 μm .

5 19 The method according to claim 8, comprising the further step of measuring metered electro-dose height using a image analyzing method and controlling height of said electro-dose to be less than 800 μm .

10 20 The method according to claim 8, comprising the further step of measuring metered electro-dose height using a combination of image analysis, laser triangulation, contrast methods to ensure a height of said electro-dose to be less than 800 μm .

15 21 The method according to claim 8, comprising the further step of measuring electro-dose deagglomeration using a Andersen Impactor for aerodynamic particle size distribution or a Malvern Mastersizer S to determine a physical particle size distribution for a calculation and optimization of deagglomeration of said electro-dose by changing its porosity.

20 22. A process of preparing doses of powder to be used for administration by a dry powder inhaler, wherein

a medical powder, being a preparation of a chemical and/or biological substance forming an electro-powder, is metered onto a device member constituting a dose carrier thereby forming a metered electro-dose;

25 a metered electro-dose bed is formed on a dose carrier material using electrical field technology;

obtained metered electro-dose bed is analyzed regarding dose height, dose area, dose de-agglomeration, dose mass, dose density, dose porosity; and

30 a result of the analysis is compared with predefined dosing parameters for deciding that the prepared metered electro-dose of powder on the dose carrier complies with the basic requirements for administration by the inhaler.

23. The process according to claim 22, wherein electrical field technology is combined with a mechanical vibration and/or an applied electrical frequency.

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24. The process according to claim 22, wherein a material of said device member is an isolative plastic material processed before dosing and metering by ionized air to remove electrostatic charges from its surface.

10 25. The process according to claim 22, wherein a material of said device member is an isolative plastic material processed before dosing and metering by introducing the device member into humid air to remove electrostatic charge from its surface.

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26. The process according to claim 22, wherein a material of said the device member is an isolative plastic material processed before dosing and metering by combination of ionized air and humid air to remove electrostatic charges from its surface.

27. The process according to claim 22, wherein said electro-conductive material is mixed into a plastic material constituting the device member.

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28. The process according to claim 22, wherein said electro-conductive material is coated onto a plastic material constituting the device member.

29. The process according to claim 27, wherein said conductive material and the plastic material combination of said device member has a specification presenting a surface resistance of 10^3 - 10^{12} Ω , and a volume resistivity of 10^3 - 10^{12} ohm·m.

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30. The process according to claim 28, wherein said conductive material and the plastic material combination of said device member has a specification presenting a surface resistance of 10^3 - 10^{12} Ω , and a volume resistivity of 10^3 - 10^{12} ohm·m.

31. The process according to claim 22, wherein said electro-conductive material used for said device member is obtained from any of materials such as silver powder, platinum powder, gold powder, stainless steel powder, antimony-doped tin oxide, antimony-doped silica oxide, or is a X-doped silica where X is an adamantine semiconductor, e.g., ZnO, GaSb or an octahedral semiconductor, e.g. SnSE, AgSbSe₂, InSb or carbon or any other electro-conductive material approved by FDA and possible to incorporate into plastics.

32. The process according to claim 22, wherein said device member is temporarily given a dissipative surface by applying a thin solvent layer onto its surface e.g. water, carbon dioxide or other non-toxic and FDA approved solvent with appropriate electrical properties by using a temperature difference or a high humidity chamber and after dosing and metering removing said solvent from said device member.

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